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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,700	10/15/2004	Monica Petronella Maria De Maat	101137-56	2836

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,700	DE MAAT ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,14-24 and 47-68* is/are pending in the application.

4a) Of the above claim(s) *10 and 14-24* is/are withdrawn from consideration.

5)☒ Claim(s) *47-53* is/are allowed.

6)☒ Claim(s) *54-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/09*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *copy of proposed ex. amendment*.

DETAILED ACTION

Claims 10, 14-24, 47-68 are pending. Claims 47-68 are considered on the merits. Claims 10, 14-24 are withdrawn from consideration as being drawn to a non-elected invention.

Applicant's election with traverse of the species, HMW content of at least 80% w/w of the total fibrinogen, in the reply filed on 8/6/09 is acknowledged. As claims 47-53 are now allowable, the search has been extended to the next species, LMW, in claims 54-66.

Applicants' attorney was faxed a proposed examiner's amendment on April 14, 2010 for reply. The attorney was called and messages were left multiple times during the course of 3 and ½ weeks in unsuccessful attempts to obtain authorization and pass the application on to allowance. As a response was not been received as of May 10, 2010, the application is now due to be acted upon by the examiner and a final action follows.

For the record, an interview summary and the proposed examiner's amendment has been appended to this action.

Claim Rejections - 35 USC § 112
enablement

Claims 54-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 54-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for topical administration of LMW fibrinogen, does not reasonably provide enablement for intravenous injection or infusion of LMW fibrinogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims appear to include administering fibrinogen by intravenous injection or infusion in order to decrease angiogenesis by forming a fibrin matrix at the site of angiogenesis.

There is no evidence in the specification or in the declarations submitted 1/28/10 which would enable one of skill in the art to administer LMW fibrinogen via intravenous injection or infusion which would form a fibrin matrix at a location which is a site of neoangiogenesis in order to slow angiogenesis.

For example, neoangiogenesis is involved in the development of retinopathy in diabetes, see Zhang *et al.* [U].

One of the problems is the targeting in the retina of the active principles when systemic intravenous injection or infusion is performed.

The only drug treatments now available for retinal angiogenesis are intravitreal administration of anti-VEGF type drugs, such as VEGF-neutralizing antibodies, see Zhang *et al.* [U], which is a contemporary review of the state of the art of potential therapies for ocular neovascularization.

Applicants have not demonstrated or supported an intravitreal administration of LMW fibrinogen for decelerating angiogenesis, which would be a treatment of diabetic retinopathy, and have not demonstrated that an intravenous injection or infusion of LMW fibrinogen can inhibit neovascularization of the retina, which is the site of angiogenesis in diabetic retinopathy. Thus, the claims are not enabled over their scope.

indefinite

Claims 54-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 54 recites topically administering to the patient at a site angiogenesis deceleration is desired, intravenous, injection or infusion of a fibrin matrix. Thus the claim does not make sense and the metes and bounds cannot be interpreted.

Claims 62 should depend on claim 54 as claim 58 appears to be duplicative and does not appear to further limit the independent claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651